DOCKET NO.: CELG-0401 **PATENT**
Application No.: 10/762,897
Notice of Allowance Dated: February 10, 2005

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Marc Elsayed and Bruce Williams

Confirmation No.: 5433

Application No.: 10/762,897

Group Art Unit: 3736

Filing Date: January 22, 2004

Examiner: Michael C. Astorino

For: Methods For Delivering A Drug To A Patient While Preventing The Exposure Of A Foetus Or Other Contraindicated Individual To The Drug

DATE OF DEPOSIT: 5/10/05

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

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Sir:

Comments on Statement of Reasons for Allowance

Applicants wish to thank the examiner for the Notice of Allowance dated February 10, 2005, indicating that claims 13-21 are allowed. Applicants are aware that the examiner's statement of reasons for allowance is the personal opinion of the examiner as to why the claims are allowable, and should not create an estoppel. M.P.E.P. § 1302.14. Furthermore, although failure of Applicants to comment on the examiner's statement of reasons of allowance should not be treated as acquiescence to the examiner's statement, Applicants submit the following comments in response to the examiner's statement of reasons for

allowance.

According to the examiner, Pissanos, *et al.*, Teagarden, *et al.*, and Mayaud each allegedly disclose various aspects of the Applicants' claimed inventions. Applicants traverse this assertion. Pissanaos, *et al.* allegedly has a filing date of February 2, 1999. The present application, (which is related to United States Patent Application No. 09/143,569 (now U.S. Patent No. 6,045,501)) claims a priority date at least as early as August 28, 1998. As such, the examiner has not demonstrated that Pissanos, *et al.* is prior art to the present invention.

Applicants' invention encompasses, *inter alia*, a method for distributing a teratogenic drug to a patient in need thereof while preventing foetal exposure to the drug, the method comprising registering in a computer readable storage medium physicians permitted to prescribe the drug; providing the patient with information concerning the teratogenic risks attendant to foetal exposure to the drug; obtaining the informed consent of the patient to receive the drug despite the risks; registering the patient in the medium, including information concerning the ability of the patient to become pregnant or to impregnate a female; upon a determination that the patient is capable of becoming pregnant or capable of impregnating a female, determining that the patient is not currently pregnant or counseling the patient capable of impregnating a female to use a contraceptive device or formulation when engaging in sexual intercourse with a female, and registering the same in the medium; and permitting the patient access to the drug only after consulting the medium to verify that the patient is a female who is not pregnant , or is a female incapable of becoming pregnant, or is a male who has been counseled to use a contraceptive device or formulation when engaging in sexual intercourse with a female. Neither Teagarden, *et al.* nor Mayaud teach or suggest Applicants' claimed inventions.

Contrary to the examiner's assertions, neither Teagarden, *et al.* nor Mayaud teach or suggest Applicants' claimed inventions. Teagarden, *et al.* and Mayaud fail to teach or suggest, *inter alia*, a method for distributing a teratogenic drug to a patient in need thereof while preventing foetal exposure to the drug. Moreover, Teagarden, *et al.* and Mayaud fail to teach or suggest providing a patient with information concerning the teratogenic risks attendant to foetal exposure to the drug, obtaining the informed consent of the patient to receive the drug despite the risks; registering the patient in the medium, including information concerning the ability of the patient to become pregnant or to impregnate a female; upon a determination that the patient is capable of becoming pregnant or capable of impregnating a female, determining that the patient is not currently pregnant or counseling the patient capable of impregnating a female to use a contraceptive device or formulation when engaging in sexual intercourse with a female, and registering same in the medium; and permitting the patient access to the drug only after consulting the medium to verify that the patient is a female who is not pregnant , or is a female incapable of becoming pregnant, or is a male who has been counseled to use a contraceptive device or formulation when engaging in sexual intercourse with a female.

Date: 5/10/05

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